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10/826,106	04/15/2004	Ronald Edward Steele	4-31394BDI	9876

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CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 104/3  
EAST HANOVER, NJ 07936-1080

EXAMINER

ROYDS, LESLIE A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/826,106

**Applicant(s)**

STEELE, RONALD EDWARD

**Examiner**

Leslie A. Royds

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-13 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/25/04 &amp; 12/20/05</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

#### **Claims 11-13 are presented for examination.**

Acknowledgement is made of the present application as a divisional application of U.S. Patent No. 10/149,107, filed August 27, 2002, now abandoned, which was a 371 National Stage entry of PCT/EP01/04116, filed April 10, 2001, which claims benefit under 35 U.S.C. 119(e) to U.S. Provisional Patent Application No. 60/196,742, filed April 12, 2000. Applicant's Preliminary Amendment filed April 15, 2004 has been received and entered into the application. Accordingly, claims 1-10 have been cancelled and claims 11-13 are newly added. Applicant's Information Disclosure Statements (IDS) filed June 25, 2004 (two pages) and December 20, 2005 (one page) have each been received and entered into the application. As reflected by the attached, completed copies of form PTO-1449 (three pages total), the Examiner has considered the cited references. Applicant's response filed July 12, 2006 to the requirement for restriction/election dated June 16, 2006 has been received and entered into the application.

#### ***Requirement for Restriction/Election***

Applicant was required under 35 U.S.C. 121 to elect a single disclosed species of disease as recited in present claim 11 for prosecution on the merits to which the claims will be restricted if no generic claim is finally held to be allowable. Claims 11-13 were identified as generic.

Applicant's election of the species of congestive heart failure as the single disclosed species of disease as recited in present claim 11 in the reply filed July 12, 2006 is acknowledged. Insofar as Applicant has failed to particularly point out the supposed errors in the requirement for election, Applicant's election has been herein treated as an election **without traverse**. Please

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reference MPEP §818.03(a).

Therefore, for the reasons above and those made of record at pages 2-6 of the previous Office Action dated June 16, 2006, the restriction requirement remains proper and is made **FINAL**.

The claims corresponding to the elected subject matter are 11-13 and such claims are herein acted on the merits.

#### ***Objection to the Claims***

Claim 13 is objected to because there is no space between “12” and “wherein” in the first line of the claim.

#### ***Objections to the Specification***

Applicant is requested to update the priority claim at page 1 following the title of the invention for completeness and also to reflect the current status of U.S. Patent Application No. 10/149,107. Applicant may wish to consider amending the priority claim to now read:

---This application is a divisional application of ~~pending~~ U.S. application Serial No. 10/149,107 filed August 27, 2002, now abandoned, which is a 371 (National Stage) application of PCT Application No. PCT/EP01/04116, filed April 10, 2001, which claims the benefit of U.S. Provisional Patent Application No. 60/196,742, filed April 12, 2000.---

The use of the trademark OPADRY has been noted in this application at page 15. Each letter of the trademark should be capitalized at every instance it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications,

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the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

***Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for delaying the progression of or treating congestive heart failure comprising the administration of an aldosterone synthase inhibitor in free or pharmaceutically acceptable salt form, does not reasonably provide enablement for the prevention of the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

- 1) the nature of the invention;
- 2) the breadth of the claims;
- 3) the predictability or unpredictability of the art;
- 4) the amount of direction or guidance presented;
- 5) the presence or absence of working examples;
- 6) the quantity of experimentation necessary;
- 7) the state of the prior art; and,
- 8) the relative skill of those skilled in the art.

The *relevant factors* are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The presently claimed invention is directed to a method for the prevention of, delay of progression of or treatment of congestive heart failure comprising the administration to a warm-blooded animal, including man, a therapeutically effective amount of a pharmaceutical composition comprising an aldosterone synthase inhibitor in free or pharmaceutically acceptable salt form. Present claims 12-13 are directed to particular aldosterone synthase inhibitors, i.e., anastrozole, fadrozole or exemestane.

In particular, one skilled in the art could not practice the presently claimed subject matter without undue experimentation because the artisan would not accept on its face that the prevention of congestive heart failure could actually be achieved. Based upon the state of the art, as discussed below, the artisan would have only accepted that the treatment or delaying the progression of congestive heart failure in a person in need thereof could be achieved with such an inhibitor.

As set forth in *In re Marzocchi et al.*, 169 USPQ 367 (CCPA 1971):

“[A] [s]pecification disclosure which contains the teachings of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with the enabling requirement of first paragraph of 35 U.S.C. 112, *unless there is reason to doubt the objective truth of statements contained therein which must be relied on for enabling support*; assuming that sufficient reasons for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs

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indicating that teaching contained in the specification is truly enabling.” (emphasis added)

The present claims circumscribe a method for preventing congestive heart failure by administering an aldosterone synthase inhibitor, such as anastrozole, fadrozole or exemestane in either free or pharmaceutically acceptable salt form. That is, in order to be enabled to practice the present invention, the skilled artisan would have to accept that by administering a pharmaceutical composition comprising such an inhibitor, patients would be protected against developing such a disorder. In other words, the skilled artisan would have understood the term “prevention”, in its broadest reasonable interpretation consistent with MPEP §2111, to mean that the incidence of developing such a condition would be essentially 0% and could be reasonably expected not to occur. In light of the fact that the specification fails to provide the skilled artisan with any direction or guidance as to how prevention of congestive heart failure could actually be achieved, since the disclosure is solely directed to the concept of treating congestive heart failure in patients that already exhibit the disease, the present specification is viewed as lacking an enabling disclosure of the entire scope of the claimed invention.

Regarding the prevention of congestive heart failure, the objective truth that such a condition may be prevented is doubted because, while the state of the art with regard to the treatment of congestive heart failure is relatively well developed, the state of the art with regard to the development of strategies or protocols aimed at the prevention of such a condition is grossly underdeveloped.

In this regard, Baker (“Prevention of Heart Failure”, *Journal of Cardiac Failure*, 2002) is cited. Baker teaches, “Treatment of hypertension reduces the incidence of HF by approximately 50%, even among very elderly patients. Diuretics, beta-blockers, and angiotensin-converting

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enzyme (ACE) inhibitors appear more effective than calcium channel blockers and doxazosin. Hydroxymethylglutaryl coenzyme A (HMG CoA) reductase inhibitors reduce the incidence of HF by approximately 20% among patients with hypercholesterolemia and coronary artery disease. ACE inhibitors reduce HF incidence by 37% among patients with reduced systolic function and by 23% among patients with coronary artery disease and normal systolic function. Observational studies have shown lower HF incidence among people with diabetes with better glycemic control. Unfortunately, all of these effective therapies appear to be underused, and control of hypertension is particularly poor.” (see abstract) It is clear from the teachings of Baker that the current state of the art with regard to the use of pharmacologic therapies to treat precipitating causes of congestive heart failure cannot be relied upon as broad preventive strategies, because the art has shown that they are capable of reducing the incidence of heart failure, but not actually definitively preventing its development.

Despite the fact that the art recognizes a variety of precipitating causes of congestive heart failure, including, but not limited to, pulmonary embolism, infection, anemia, thyrotoxicosis, pregnancy, arrhythmias, rheumatic fever and other forms of myocarditis, infective endocarditis, physical, dietary, environmental and emotional excesses, systemic hypertension and myocardial infarction (see Harrison’s Principles of Internal Medicine, Ninth Edition, cited by Applicant), the fact that a patient may fit into any one or more of such criteria does not necessarily mean that the patient is predisposed to developing congestive heart failure. In other words, the art recognizes the variability among individual patients and the risk factors they exhibit preclude a common, art-accepted protocol for preventing congestive heart failure in all patients, given that each patient has risk factors or circumstances unique to that individual that



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must be considered when determining the most effective approach to preventing congestive heart failure.

Given the state of the art, which recognized the great variability in patients in need of prevention of congestive heart failure and the inability to create an art-accepted prevention strategy due to these differences, one of ordinary skill in the art would not accept on its face Applicant's statement that the therapeutic objective of prevention could actually be achieved. The artisan would have required sufficient direction as to how, at minimum, the population of patients in need of prevention of congestive heart failure could have been readily identified without requiring an undue level of experimentation such that the skilled artisan would have been imbued with at least a reasonable expectation of success in identifying such patients and actually preventing the development of congestive heart failure. Such success would not have been reasonably expected in light of what is presently disclosed because Applicant has failed to provide any guidance as to how such a population of patients would be identified such that the presently claimed agent(s) could actually be used for achieving the objective of prevention. Absent this disclosure, the present specification fails to enable the full scope of this invention as it relates to the objective of prevention and, thus, fails to rebut the presumption of unpredictability in the art with regard to this same objective.

It is in this regard that Applicant is directed to the MPEP at §2164.08. All questions of enablement are evaluated against the claimed subject matter. Concerning the breadth of a claim relevant to enablement, the only relevant concern is whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. The determination of the propriety of a rejection based upon the scope of a claim

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relative to the scope of enablement involves the determination of how broad the claim is with respect to the disclosure and the determination of whether one skilled in the art is enabled to use the *entire scope* of the claimed invention without undue experimentation.

Applicant provides examples of various pharmaceutical formulations that may be employed in the disclosed method, but does not present any examples directed to the actual practice of the presently claimed method. While a lack of a working embodiment cannot be the sole factor in determining enablement, the absence of substantial evidence commensurate in scope with the presently claimed subject matter, in light of the unpredictable nature of the art and the direction that Applicant has presented, provides additional weight to the present conclusion of insufficient enablement in consideration of the *Wands* factors as a whole. The instant specification conspicuously lacks any disclosure or teaching of manner and process of using the presently claimed agent(s) for achieving the objective of prevention of congestive heart failure. Nowhere does the specification disclose how those patients at risk for developing such a condition could be identified, what criteria would be used to determine such patients and how they would be treated using the presently claimed agent(s) such that the skilled artisan would have been imbued with at least a reasonable expectation of success in determining such patients without the burden of an undue level of experimentation. Due to the unpredictable nature of the pathophysiological manifestations of congestive heart failure, and in the absence of any guidance or direction as to how the skilled artisan would go about identifying patients in need of prevention, the instant disclosure is viewed as lacking enablement for this aspect of the present invention.

In view of the discussion of each of the preceding seven factors, the level of skill in the

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art is high and is at least that of a medical doctor with several years of experience in the art.

As the cited art and discussion of the above factors establish, practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation that the prevention of congestive heart failure could be achieved. In order to actually achieve such a result, it is clear from the discussion above that the skilled artisan could not rely upon Applicant's disclosure as required by 35 U.S.C. 112, first paragraph, and would have no alternative recourse but the impermissible burden of undue experimentation in order to practice the full scope of the presently claimed invention.

***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is

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(a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claim 11 recites the broad limitation “comprising administering to a warm-blooded animal”, and then goes on to state, “including man”, a narrower statement of the limitation. Such a recitation renders the claim indefinite because it is unclear as to whether Applicant intends to claim the administration of the presently claimed combination of agents for the treatment of congestive heart failure in any warm-blooded animal, or if Applicant intends to claim the administration of the presently claimed combination of agents for the treatment of congestive heart failure in man only. As a result, the boundaries of the claim cannot be readily identified.

For these reasons, claims 11-13 fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

For the purposes of examination and the application of prior art, the claims will be interpreted to read upon the administration of the presently claimed combination of agents for the treatment of congestive heart failure in any warm-blooded animal.

Claims 11-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, it is noted that present claim 11 reads upon a method for the prevention of,

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delay of progression of or treatment of congestive heart failure. However, Applicant has failed to connect the preamble objective of treating congestive heart failure to the subject to be treated. For example, it is not clear whether the subject of the claim is a subject suffering from congestive heart failure or whether it is another subject that does not suffer from heart failure or may be at a high risk for developing such a condition. In other words, Applicant has not made clear on the record whether the subject is one in need of treatment of congestive heart failure or is one in need of treatment of any other condition.

For these reasons, the metes and bounds of the present claims cannot be identified and one of ordinary skill in the art would not necessarily be reasonably apprised of the scope of the claims. In light of such, claims 11-13 fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alexander et al. (WO 96/40257; 1996) in view of Trunet et al. ("The Effects of Fadrozole Hydrochloride on Aldosterone Secretion in Healthy Male Subjects", 1992), Haeusler et al. ("Evidence that Corticosterone Is Not an Obligatory Intermediate in Aldosterone Biosynthesis in the Rat

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Adrenal", 1989) and Furet et al. ("Aromatase Inhibitors: Synthesis, Biological Activity and Binding Mode of Azole-Type Compounds", 1993).

Alexander et al. teaches a pharmaceutical composition comprising a therapeutically effective amount of an epoxy-steroidal aldosterone receptor antagonist and a therapeutically effective amount of an angiotensin II receptor antagonist, and the enantiomers or pharmaceutically acceptable salts of either compound (see page 170, lines 14-18) for the treatment of congestive heart failure (see page 8, first paragraph in full and also claims 19 and 21).

The differences between the Alexander et al. reference and the presently claimed subject matter lie in that the reference does not teach the use of an aldosterone synthase inhibitor (e.g., fadrozole etc.) as the aldosterone-blocking agent.

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because Trunet et al. and Haeusler et al. provide teachings that the compound fadrozole was known in the art to impair basal aldosterone secretion in healthy male volunteers (see abstract of Trunet et al.) and CGS-16949A (also known as fadrozole hydrochloride; see abstract of Furet et al.) was able to inhibit aldosterone biosynthesis at concentrations 100 times lower than those necessary for the inhibition of corticosterone biosynthesis (see abstract of Haeusler et al.). Furet et al. is further relied upon to show that the (+) enantiomer of fadrozole hydrochloride was isolated and well known in the art at the time of the invention (see first paragraph at page 1393 under the heading "Chemistry and Biological Properties").

The skilled artisan would have been motivated to use the aldosterone synthase inhibitor in place of the aldosterone receptor antagonists taught by Alexander et al. because each was recognized to be functionally equivalent for the same purposes in the prior art, namely that each type of compound has a similar effect of blocking aldosterone. Regardless of whether the bioavailability of aldosterone was blocked by antagonizing the aldosterone receptor by the epoxy-steroidal compounds taught by Alexander et al. or by inhibiting the synthesis of aldosterone, the ultimate effect of each genus of compounds (i.e., the aldosterone receptor antagonists or the aldosterone synthase inhibitor fadrozole) would have been reasonably expected to be the same. Thus, substituting the aldosterone receptor antagonists with an aldosterone synthase inhibitor in the composition disclosed by Alexander et al. would have been *prima facie* obvious and well within the purview of the skilled artisan because the same end result of blocking the bioavailability of aldosterone would have been achieved.

The MPEP states at §2144.06, “In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant’s disclosure or the mere fact that the components at issue are functional or mechanical equivalents.” Because the Examiner has shown that the functional equivalency of the compounds was known in the prior art at the time of the invention, the present finding of obviousness is proper and firmly grounded in the teachings of the MPEP at §2144.06.

Applicant’s attention is further drawn to the MPEP at §2144.06, which states, “An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982).”

Applicant is reminded that the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

***Subject Matter That Does Not Appear to be Suggested by the Prior Art***

The state of the prior art at the time of the present invention appears to be such that the use of anastrozole or exemestane as an aldosterone synthase inhibitor for the treatment of congestive heart failure would not have been fairly suggested by the prior art. Both compounds are known in the art as antineoplastic agents (see Shashoua et al., U.S. Patent No. 5,795,909; cols. 31-32, for example), or useful for the treatment of hypertension, impotence, osteoporosis or cardiovascular disease (see Chwalisz et al., U.S. Patent No. 5,906,987; col.3, lines 38-45). While it is noted that the disclosure of Chwalisz et al. teaches that aromatase inhibitors such as anastrozole or exemestane may be used in combination with a nitric oxide synthase substrate, such is not particularly suggestive of anastrozole or exemestane in the treatment of the specific condition of congestive heart failure. The genus of "cardiovascular disease" is considered by the Examiner to be sufficiently large to not anticipate or render obvious the use of anastrozole or exemestane in the treatment of congestive heart failure in particular.

Moreover, the Examiner has been unable to determine that the art at the time of the invention recognized aromatase inhibitors, such as anastrozole or exemestane, as having activity in inhibiting the synthesis of aldosterone. In the absence of such knowledge, it would not have been obvious to the skilled artisan to employ either anastrozole or exemestane in the compound disclosed by Alexander et al. because the prior art did not recognize the compounds as being



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functionally equivalent to the aldosterone receptor antagonists taught by the reference. As a result, a rejection under 35 U.S.C. 103(a) asserting that the use of such aldosterone synthase inhibitors (i.e., anastrozole or exemestane) would have been obvious was not made because it would have been improper and contradictory to the teachings of the MPEP at §2144.06, which clearly directs against making such rejections.

### ***Double Patenting***

#### **Obviousness-Type Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-15 of copending U.S. Patent Application No. 11/291,008.

This is a provisional obviousness-type double patenting rejected because the conflicting claims have not in fact been patented.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the copending claims clearly anticipate the subject matter of the pending claims. Copending claim 11 expressly provides for delaying the progression of or treating congestive heart failure using an aldosterone synthase inhibitor in free or pharmaceutically acceptable salt form, particularly anastrozole, fadrozole, fadrozole hydrochloride or exemestane as recited in copending claims 11-13. In light of such, the subject matter of the present claims is clearly anticipated by the copending claims.

Accordingly, claims 11-13 are properly rejected under the judicially created doctrine of obviousness-type double patenting over claims 11-15 of copending U.S. Patent Application No. 11/291,008 as claiming obvious and unpatentable variants thereof.

### ***Conclusion***

Rejection of claims 11-13 is deemed proper.

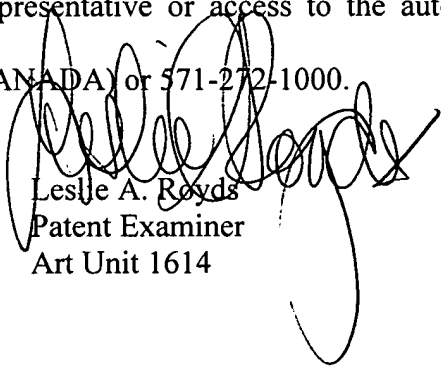
No claims of the present application are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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